



United States Representative

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Representing the Third District of Connecticut

### **Keep Infant Formula Safe and on the Shelves Act**

The current infant formula crisis facing America's babies and their caregivers is a crisis of both safety and supply. At least two babies died, and several others were hospitalized after consuming contaminated infant formula. And for the past several months, parents all over the country have been struggling to find safe formula to feed their babies.

We need to address the root causes of this crisis to ensure this cannot happen again. The *Keep Infant Formula Safe and on the Shelves Act* will improve product safety, maintain infant formula supply, and keep workers safe. The legislation would increase the Food and Drug Administration's (FDA) inspection frequency and reporting for infant formula manufacturing facilities, build a supply infrastructure to ensure that we have safe infant formula readily available, and clarify that the Defense Production Act can be invoked if any food-related shortages occur.

In the wealthiest nation in the world, babies should not be at risk of going hungry. Parents should not have to play a guessing game and wonder if what they are feeding their babies is safe. But unfortunately, that is where corporate greed, market consolidation, and a lack of proper oversight have led us.

In the short term, it is vital that we get safe infant formula back on the shelves. In tandem with Operation Fly Formula and the invocation of the Defense Production Act, we are securing safe infant formula and importing it swiftly to meet this urgent supply need. But we must do more.

Specifically, the *Keep Infant Formula Safe and on the Shelves Act* includes the following provisions:

#### **PRODUCT SAFETY**

- Increases the FDA inspection frequency for facilities producing infant formula.
- Includes unannounced inspections for facilities, even if the most recent inspection report for a facility encountered no problems (notable regulatory findings).
- Increases the frequency of audits based on cause and requires facilities to make all microbial test results available to the FDA during audits and inspections.

- Requires automatic comprehensive food safety audit analysis that includes enhanced testing if problems (notable regulatory findings) are found during an inspection.
- Directs the Centers for Disease Control and Prevention (CDC), in consultation with the Council of State and Territorial Epidemiologists, to work together to make *Cronobacter sakazakii* a reportable disease.

## **SUPPLY INFRASTRUCTURE**

- Clarifies the Defense Production Act (DPA), so that the DPA can be invoked for any food-related shortage, including infant formula and its ingredients. Given there may be a global food shortage from the current crisis in Ukraine, this bill ensures the DPA can be invoked, if needed.
- Directs relevant agencies to perform an assessment of short- and long-term storage of infant formula, including in a stockpile, and distribution models during shortages.
- Gives the FDA new authority to help prevent this type of situation from happening in the future by adopting a monitoring system requiring manufacturers of infant formulas or essential medical foods to notify the FDA when they become aware of a circumstance that could lead to a shortage of these products.
- Requires the FDA to identify manufacturing facilities that could be converted into producing infant formula that could be used if a shortage happened again and require the FDA to update the list of potential manufacturing facilities every year.
- Establishes a national infant formula registry by product and brands through the FDA as to which major retailers have formula and in what store locations to be used if a shortage happened again.

## **WORKER SAFETY**

- Directs the Department of Labor (DOL) to issue fact sheets and technical assistance to manufacturing facilities to ensure that any increase in production will not result in a decrease in safety for workers.